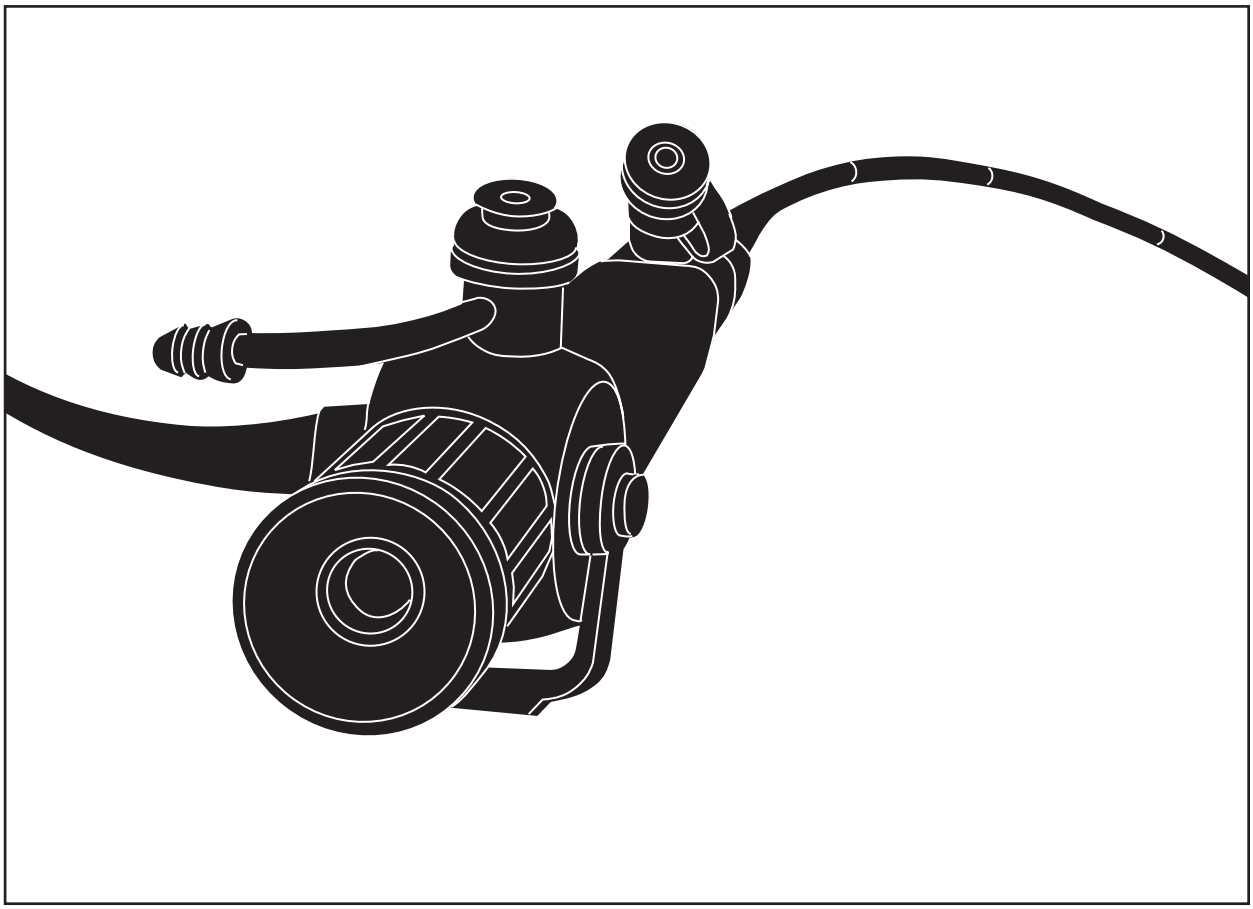
FL-100
Intubating Fiberscope

Owner's Manual



Welch Allyn®

Thank you for purchasing the Welch Allyn FL-100 Intubating Fiberscope and Light Source. The operating and maintenance instructions found in this manual should be followed to ensure many years of reliable service. Please read these instructions thoroughly before attempting to use your new instrument.

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CONVENTIONS

GENERAL PRECAUTIONS

The user of the FL-100 instrument should be thoroughly trained in the techniques of upper airway endoscopy. This instrument is specifically designed to assist endotracheal intubation as well as diagnosis in the Upper Airway. Do not use the FL-100 for any purpose other than that for which it is designed.

This manual describes the procedures for inspecting and preparing the instrument for use. It does not describe the performance of an endoscopic procedure or any of the medical aspects of endotracheal intubation. This instrument should only be used by physicians or practitioners trained in its use.

Failure to read and understand the material contained in this manual could result in patient injury. Also, failure to follow the instructions provided herein could result in malfunction and/or damage to the instrument.

This manual contains instructions on the maintenance and reprocessing of the FL-100. Every effort has been made to ensure that the listed disinfecting and sterilizing solutions and/or processes are compatible with this instrument and are effective. Since infection control practices are constantly changing, Welch Allyn recommends that the user remain aware of the latest practices and any federal, local, or hospital regulations pertaining to this very important issue.

SYMBOLS

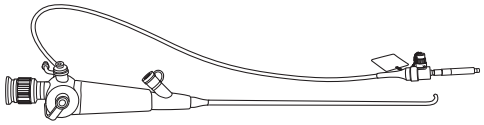
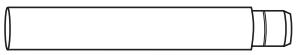
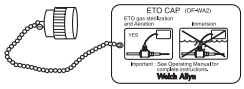
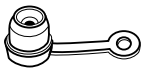
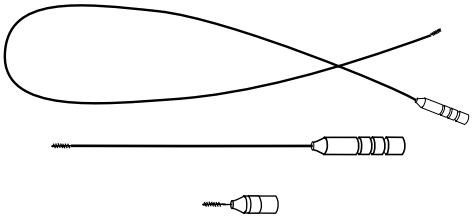
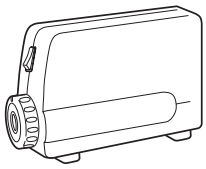
WARNING: Indicates a potentially hazardous situation which, it not avoided, could result in death or serious injury.

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or property damage.

NOTE: Indicates a potentially hazardous situation which, if not avoided, may result in property damage. Also, advises owner/operator about important information on the use of this equipment.

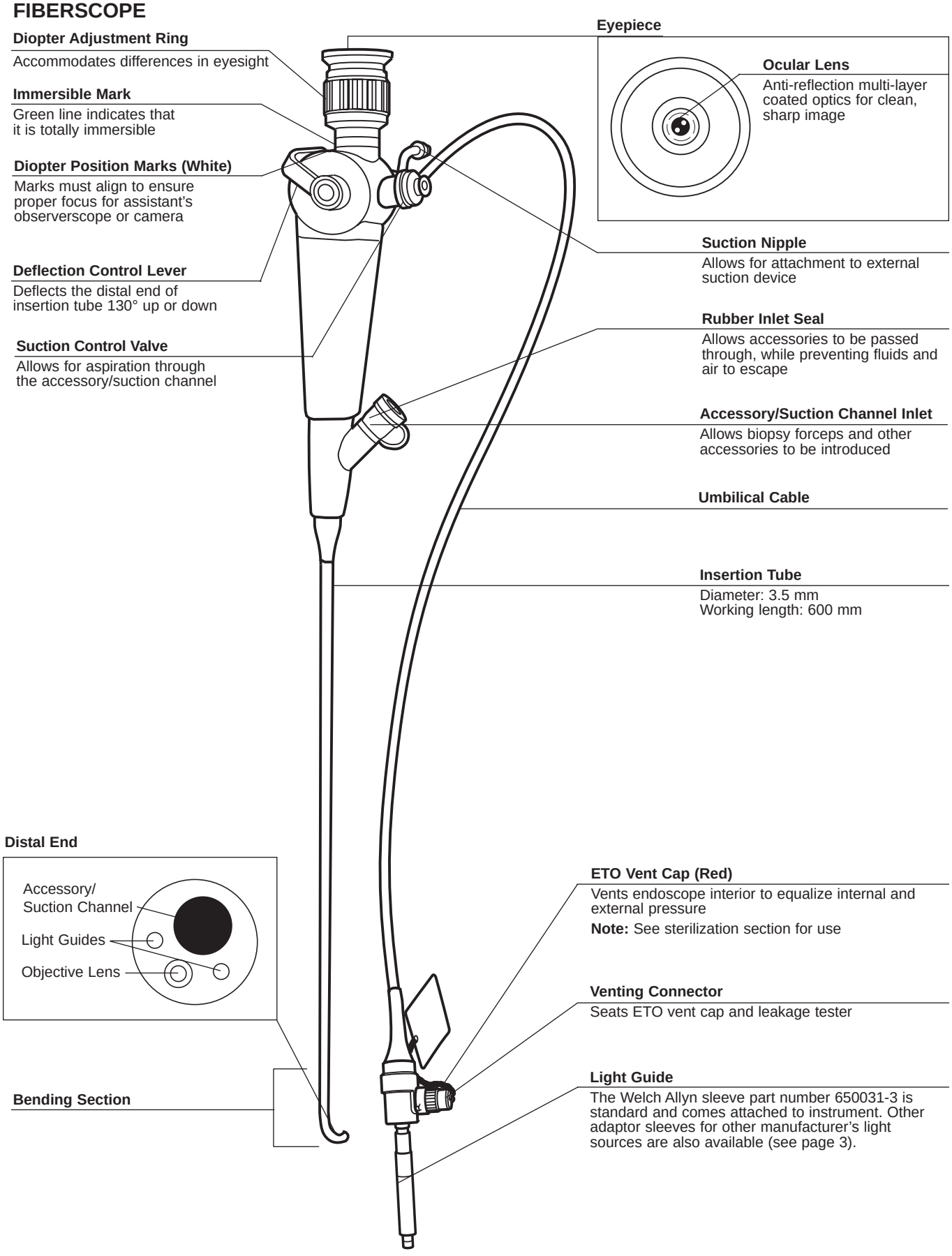
CAUTION: Federal Law (U.S.A.) restricts this device to sale by/to or on the order of a physician or other appropriately licensed medical professional.

COMPONENTS

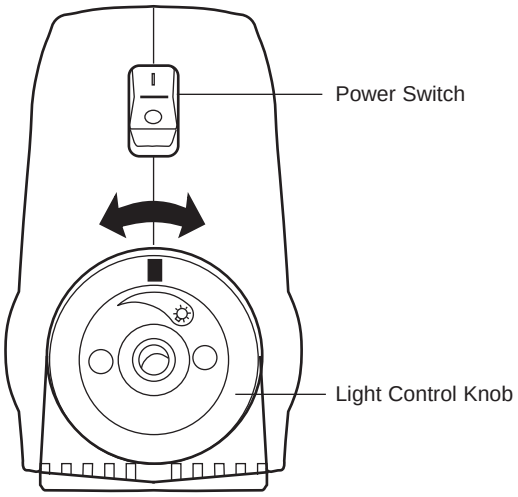
	Description	Components/Qty.	Accessories/Qty.
	Fiberscope	65300 FL-100 Intubating Fiberscope (1)	
	Light Adaptor	650031-3 Welch Allyn ACMI Adaptor (1)	65017 WA ACMI 65004 Olympus CLK-3 65005 Olympus CLK-4 65010 Olympus ILK-3 65011 Machida 65014 Pentax 65016 Wolf 65018 Storz
	Cap	650008 Eyepiece Cap (1)	
	Vent Cap	650028 ETO Vent Cap & Tag (1)	65012 each
	Cleaner	650007 Lens Cleaner (1)	65304 each
	Valve	653014 Rubber Suction Control Valves (3)	65304 each
	Seal	310183 Rubber Inlet Seals (10)	31039 (5)
	Brushes	653012 Long 653011 Short 653010 Suction Cylinder	65302 Brush Set (Long, short and suction cylinder)
	Cap	653013 Suction Cylinder Closure Cap (1)	65303 each
			49500 Welch Allyn Light Source
			65009 Leakage Tester

NOMENCLATURE AND FUNCTION

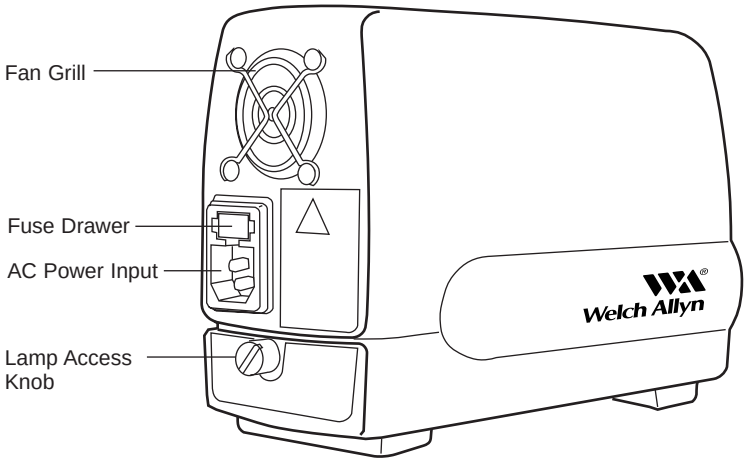
FIBERSCOPE


Eyepiece
Ocular Lens
Anti-reflection multi-layer coated optics for clean, sharp image
Diopter Adjustment Ring
Accommodates differences in eyesight
Immersible Mark
Green line indicates that it is totally immersible
Diopter Position Marks (White)
Marks must align to ensure proper focus for assistant's observerscope or camera
Deflection Control Lever
Deflects the distal end of insertion tube 130° up or down
Suction Control Valve
Allows for aspiration through the accessory/suction channel
Suction Nipple
Allows for attachment to external suction device
Rubber Inlet Seal
Allows accessories to be passed through, while preventing fluids and air to escape
Accessory/Suction Channel Inlet
Allows biopsy forceps and other accessories to be introduced
Umbilical Cable
Insertion Tube
Diameter: 3.5 mm
Working length: 600 mm
Distal End
Accessory/ Suction Channel
Light Guides
Objective Lens
Bending Section
ETO Vent Cap (Red)
Vents endoscope interior to equalize internal and external pressure
Note: See sterilization section for use
Venting Connector
Seats ETO vent cap and leakage tester
Light Guide
The Welch Allyn sleeve part number 650031-3 is standard and comes attached to instrument. Other adaptor sleeves for other manufacturer's light sources are also available (see page 3).

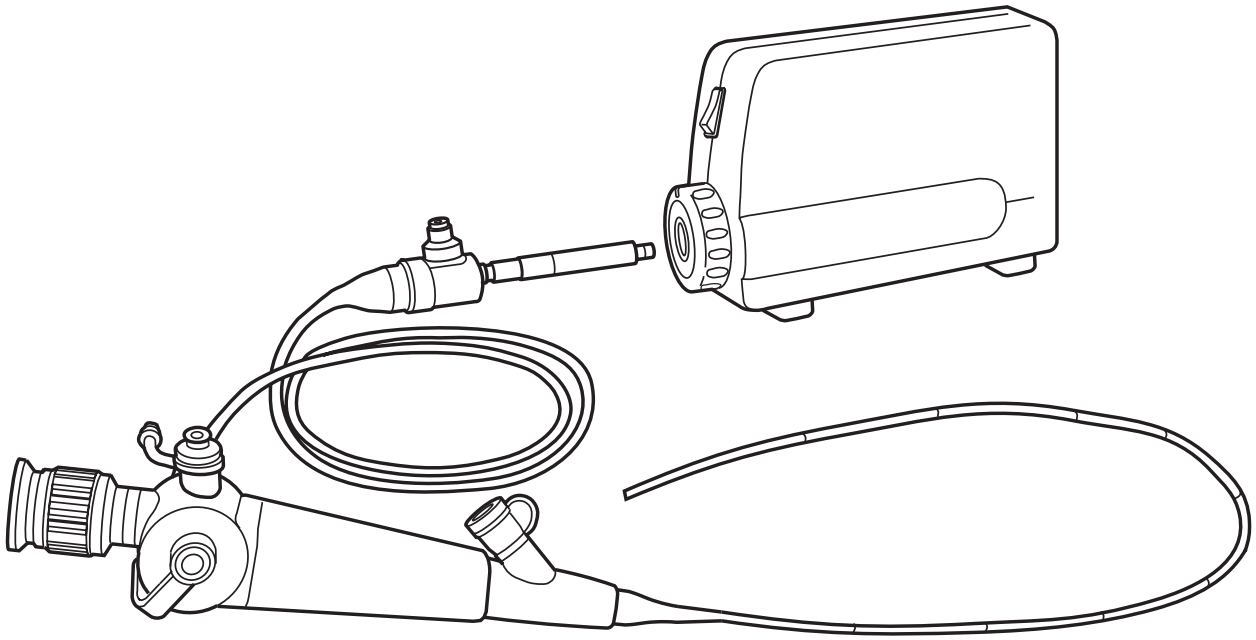
LIGHT SOURCE



FRONT

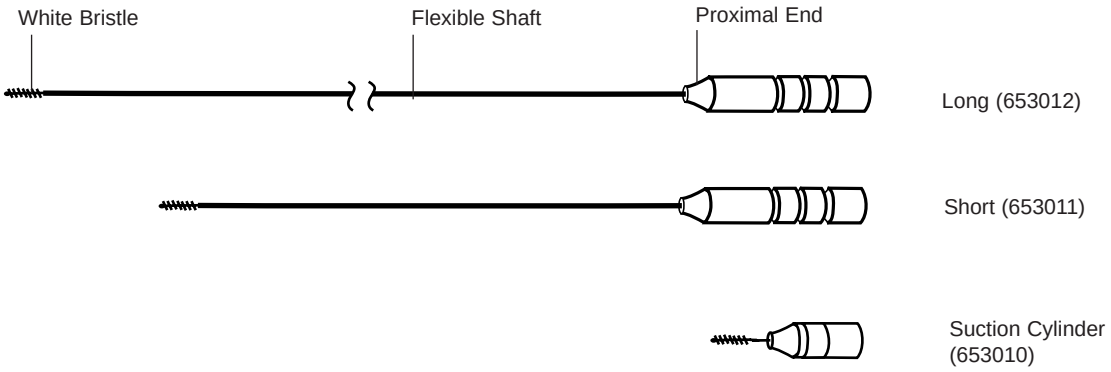


BACK



ACCESSORIES

WELCH ALLYN LIGHT SOURCE (49500) CLEANING BRUSHES



CAUTION: It is strongly recommended that only Welch Allyn accessories be used with the Welch Allyn FL-100 Intubating Fiberscope. Other accessories may adversely affect the performance of the fiberscope. If a unique or highly specialized accessory from another source is required, please contact Welch Allyn to arrange a test of its compatibility before using it with the Welch Allyn FL-100 Intubating Fiberscope.

PHOTOGRAPHIC EQUIPMENT

The Welch Allyn FL-100 Intubating Fiberscope is equipped with a universal eyepiece that will accommodate most camera adaptors.

PREPARATION AND INSPECTION FOR USE

Prior to use, the endoscope, light source and accessories must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use.

INSPECTION OF LIGHT SOURCE

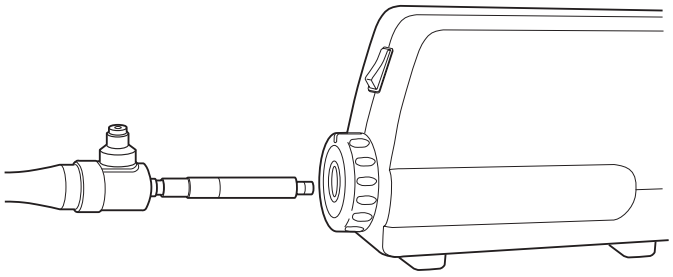
Please refer to the operating manual of your Welch Allyn Light Source for complete instructions.

CAUTION: Verify that the supply voltage matches the voltage range indicated on the rear of the Welch Allyn Light Source.

To prevent temporary blinding, turn power on only after the fiber optic bundle is plugged in and the intensity control knob is set to the minimum position.

The fiber optic bundle port is hot when fiber optic bundle is removed.

1. With the power switch in OFF position, plug light source into a properly grounded hospital grade receptacle. Welch Allyn light sources are equipped with a hospital grade plug and grounding conductor.
2. The standard Welch Allyn adaptor sleeve included on FL-100 allows connection to and light transmission from any Welch Allyn light source.
3. Depending upon the manufacturer, model and/or type of light source to be used, an adaptor may be needed to make a complete connection between the source of illumination and the Welch Allyn FL-100 fiberscope. This depends on the manufacturer, model and/or type of light source. For assistance, please contact your local Welch Allyn distributor or service facility.
4. Connect the endoscope light guide plug to the light source.
5. Turn on the light source to check for proper functioning.



NOTE: Be sure that the correct adaptor is being used for light sources other than Welch Allyn.

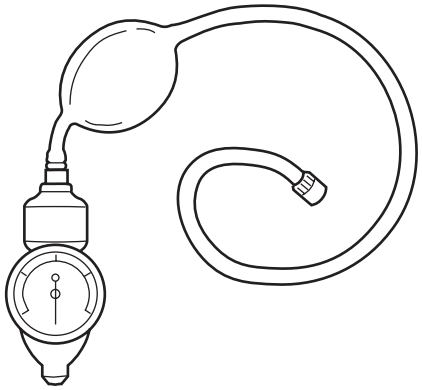
WARNING: The risk of thermal injury exists whenever fiber optic instruments are used with high intensity light sources.

The risk of injury is greatest:
- When a high intensity light source, such as the Welch Allyn HI•Lux lamp, is used.
- During close stationary observation and/or prolonged close contact with mucosa.
- When the fiberscope is advanced slowly through a narrow lumen.

Close stationary viewing should be avoided and the level of illumination should be limited to the level necessary for adequate visualization.

INSPECTION OF FIBERSCOPE

Before proceeding, the Welch Allyn FL-100 fiberscope should be tested for water-tight integrity (example: tear in the accessory/suction channel). To perform this test, see the “Leakage Test Instructions” section (page 27).



Leakage Tester

1. INSPECTION OF THE INSERTION TUBE

a) Check the entire surface of the insertion tube to assure that abnormal conditions such as bite marks, wrinkles and dents are not present. Any indentation in the flexible shaft of the fiberscope can cause damage to the fiber optics and internal mechanisms of the fiberscope.

b) Check the umbilical cable for outward signs of damage such as buckling, pinch marks, etc.

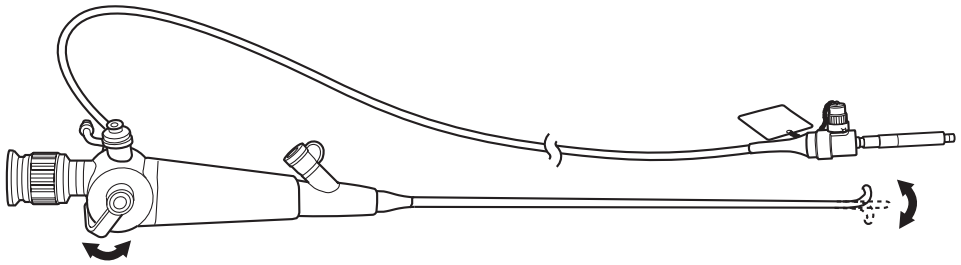
CAUTION: Do not use any fiberscope with outward signs of damage. An outwardly damaged fiberscope may cause malfunction during a procedure and further damage the scope.

c) Be sure the entire fiberscope is clean and has been subjected to either a high-level disinfection or sterilization process before each patient use.

NOTE: The distal end of the fiberscope must be protected against damage from impact. Never apply excess force such as twisting or severe bending of the flexible portion of the fiberscope.

2. INSPECTION OF DEFLECTION CONTROL

To assure smooth articulation, slowly manipulate the deflection control lever. Be sure that a full and appropriate range of deflection is possible.

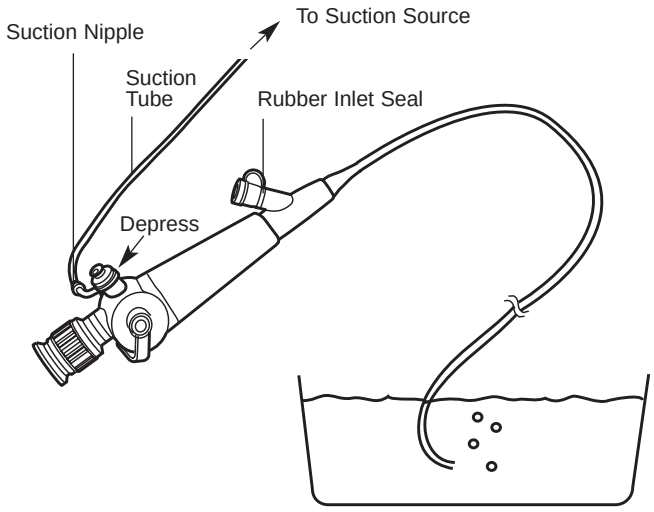


CAUTION: If the deflection control lever is not operating smoothly, this may indicate internal damage to the fiberscope. To avoid the possibility of further damage or malfunction during a procedure, never use the fiberscope if the deflection control lever is not operating smoothly.

3. SUCTION MECHANISM

a) Connect suction tubing from an external suction source to the suction nipple located on the control body. Place the distal tip of the endoscope in a basin of water and depress the suction control valve. Water should be rapidly aspirated into the suction system collection container.

b) Release the suction control valve to determine if the valve freely returns to its OFF position and the aspiration of water ceases.



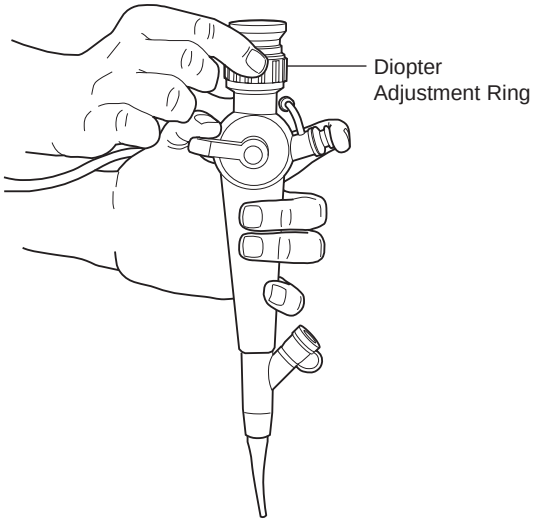
NOTE: A rubber inlet seal in good condition must be on the accessory channel inlet to prevent the loss of suction. Worn seals will result in leakage and should be replaced.

PREPARATION PRIOR TO INSERTION OF FIBERSCOPE

WARNING: Every fiberscope should be properly disinfected or sterilized before each use.

Current infection control guidelines require that endoscopes and their patient contact accessories either be sterilized or at least be subjected to high-level disinfection. Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use.

1. If needed, gently clean the objective lens with a cotton-tip applicator moistened with alcohol. A lens cleaner (anti-fogging agent) may also be applied with gauze or appropriate applicator.
2. The user should adjust the diopter adjustment ring to make sure that a clear view can be obtained. (No further adjustment should be necessary during a procedure.)
3. Use a bite block on the insertion tube to protect the insertion tube after the scope is introduced.
4. Apply a medical grade water soluble lubricant to the insertion tube. **DO NOT** use petroleum-based lubricants.



CAUTION: Never allow excessive lubricant or lens cleaner on the object lens.

OPERATION

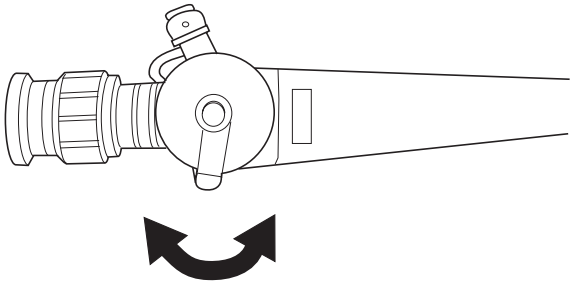
WARNING: This instrument should only be used by qualified physicians who are thoroughly familiar with all the characteristics of this instrument and who are well-versed in the proper techniques of endoscopy.

PRETREATMENT

1. The patient should be prepared in the normal endoscopy regimen.

INSERTION AND WITHDRAWAL

1. Slowly insert the scope under direct vision. As the distal end of the scope passes through the pharynx, the patient should gently bite down on the bite block to maintain the bite block's position during the procedure.
2. Adjust the intensity of the light source to obtain a brightness level suitable for observation.
3. The deflection control lever should be adjusted to properly position the scope. The deflection of the tip should be done under direct vision in a gentle and in a deliberate manner.
4. If bronchial secretions or other debris are present in the lungs making observation difficult, suctioning should be performed.
5. Photography can be carried out as necessary.
6. Always withdraw the scope under direct visualization.



WARNING: If for any reason the image is lost due to power shortage, lamp or light source failure, etc., straighten the scope tip to its neutral position, and then carefully and slowly withdraw the insertion tube from the patient.

CARE AFTER USE

IMPORTANT INSTRUCTIONS

Cleaning-Disinfection-Sterilization: Welch Allyn Endoscopes

Endoscopic instruments should be properly cleaned immediately after each use, to maintain maximum performance and a long service life for the fiberscope. If the fiberscope is left uncleaned for some time after use, dried blood, mucous or other debris may cause damage to the instrument and may interfere with the reprocessing ability of the instrument.

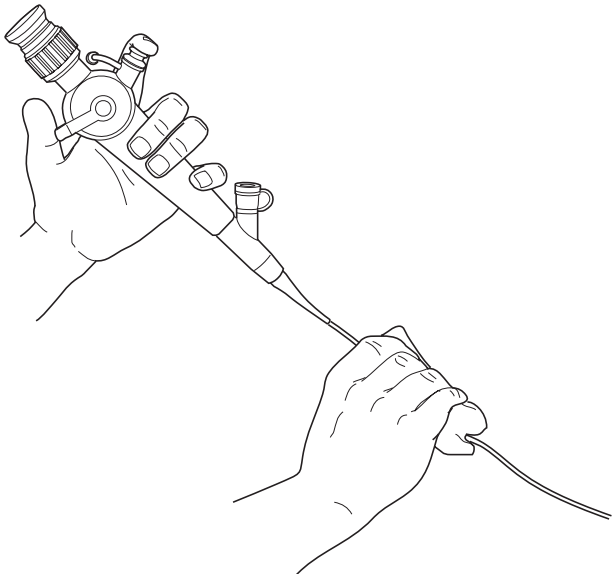
WARNING: The importance of meticulous cleaning of the endoscope cannot be over-emphasized.

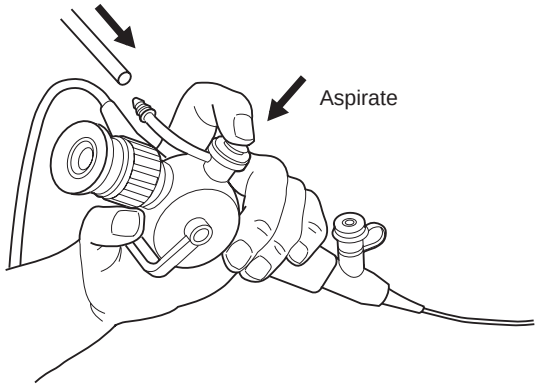
Prior to disinfection or sterilization, all instruments must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective disinfection and sterilization.

CARE AFTER EACH PROCEDURE

PRE-CLEANING AT THE EXAMINATION ROOM

1. Immediately after removing the fiberscope from the patient, gently wipe all debris from the insertion tube with a gauze moistened with an enzymatic cleaning solution. (See page 15 for a list of compatible detergents.)
2. Place the distal end of the fiberscope into detergent solution and aspirate through the channel for 5-10 seconds. Alternate aspiration of solution and air several times to create agitation for better pre-cleaning.



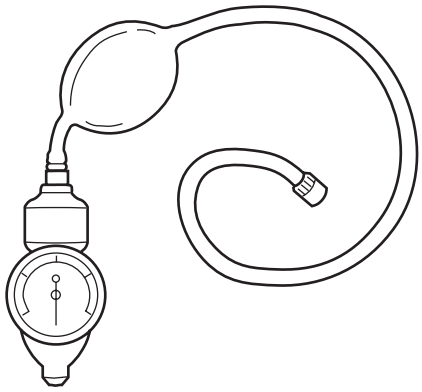


CLEANING AT THE WORK ROOM

1. The fiberscope should be Leak Tested before proceeding with any further cleaning steps.

NOTE: See section on Leakage Tester Instructions. The hand-operated Welch Allyn Leakage Tester is available as an optional accessory.

2. Prepare a basin with warm water and a mild enzymatic detergent.

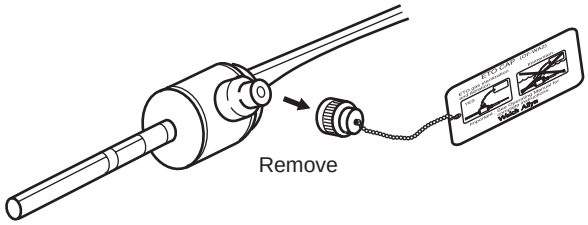


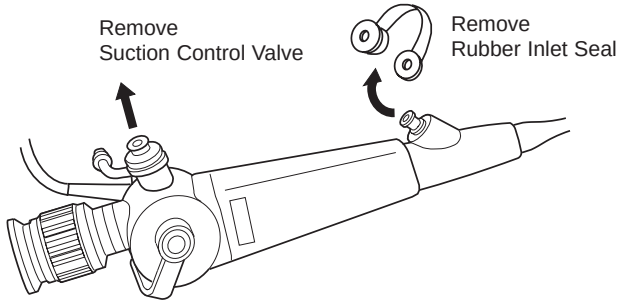
CAUTION: BEFORE IMMERSING: Take OFF the “Red” ETO gas sterilization venting cap.

The use of an enzymatic detergent immediately after each procedure to dissolve and remove organic contaminants and proteinaceous debris is essential to the care and maintenance of the endoscope from the standpoints of infection control and functionality.

3. Remove the rubber suction control valve and the rubber inlet seal. Then thoroughly (but gently) wash the entire surface of the endoscope and its components. Allow all items to soak in an enzymatic solution for the time period recommended by the manufacturer of the enzymatic detergent.

NOTE: Do not squeeze or severely bend the insertion tube. Do not use any abrasive materials. Be careful to avoid damage to the distal lenses.





4. A variety of special brushes are provided to clean the entire suction system. Brush clean the entire accessory/suction channel:

    a) Use the short cleaning brush and insert the brush into the opening of the suction nipple. Gently pass the brush until it appears in the suction control valve receptacle. Repeat several times (see Figure 1).

    b) Next, insert the same short brush into the opening at the bottom of the suction control valve receptacle (cylinder) on the control head (see Figure 2) and gently advance until resistance is felt (approximately 12 cm). DO NOT USE EXCESS FORCE. Gently withdraw the brush. Repeat several times.

NOTE: Be sure to inspect the bottom of the suction control valve receptacle on the control head for any debris.

    c) Insert the long brush into the accessory/suction channel inlet port and gently advance the brush until it exits the distal end of the scope. Clean debris off the brush and then gently withdraw the brush (see Figure 2).

    Repeat several times ensuring that only a clean brush is introduced into the channel each time.

    d) Using the specially designed suction cylinder cleaning brush, scrub clean the surfaces inside the suction control valve receptacle on the control head (See Figure 3).

5. Install the suction cylinder closure cap as illustrated.
6. With the rubber inlet seal in place, a large luer slip syringe can be attached to the end of the suction nipple and used to flush enzymatic detergent solution into the entire accessory/suction channel. Be sure the detergent solution is allowed to remain in contact with the internal channel surfaces for the recommended exposure time. The enzymatic detergent should dissolve and/or dislodge any debris that may be within these internal areas.
7. After the scope has been exposed to the detergent solution for an appropriate time, flush the accessory/suction channel with air to purge remaining detergent.

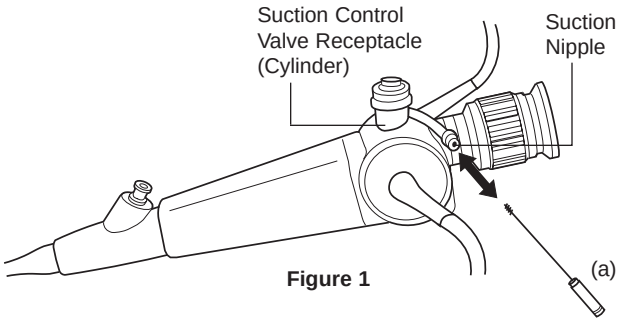


Figure 1

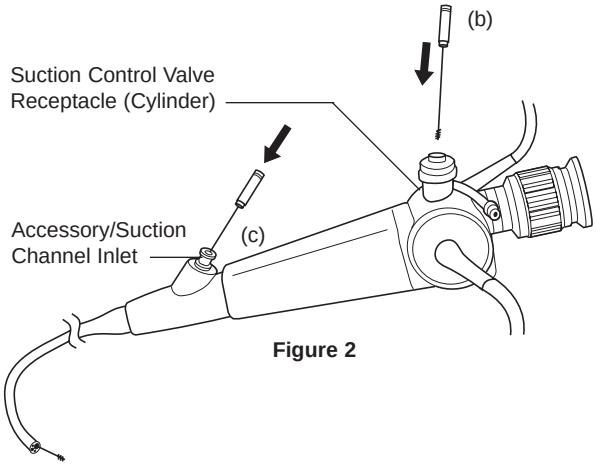


Figure 2

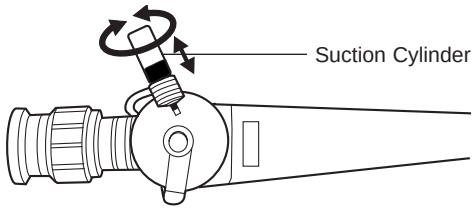


Figure 3

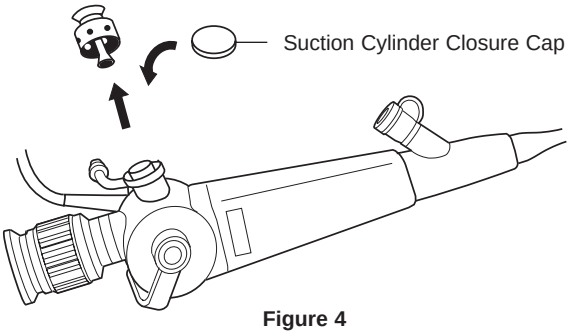


Figure 4

WARNING: The enzymatic detergent solution should remain in contact with ALL internal channels and external scope surfaces for the time period recommended by the manufacturer of the detergent.

8. Rinse the entire scope and all its components with clean water.

9. The entire accessory/suction channel should aIso be rinsed free of residual detergent using one of the following methods:

   a) With the suction cylinder closure cap still in place, fill a syringe with clean water and flush the accessory/suction channel.

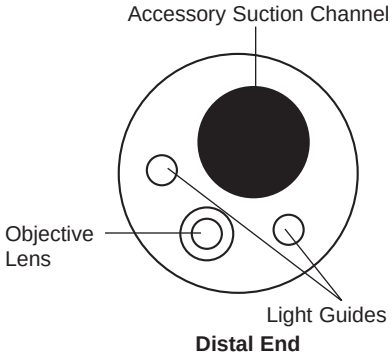
   b) With the rubber inlet seal still in place, reinstall the rubber suction control valve and aspirate clean water through the entire channel of the scope.

WARNING: It is important that ALL internal channels, external scope surfaces and components be thoroughly rinsed with water to remove residuaI detergent solution.

10. Purge water from the accessory/suction channel and scope components.

NOTE: 70% alcohol followed by compressed air, not greater than 24 PSI, may be used to facilitate drying.

11. Gently dry all external surfaces of the fiberscope with a soft gauze. Do not put tension on the insertion tube of the endoscope while drying, since the outer cover of the bending section may be excessively stretched. Dry the objective lens with a cotton tip applicator.



Distal End

ENZYMATIC CLEANING SOLUTIONS*

Specific reference to brand names is not an endorsement of their efficacy as a cleaning solution. Tests have shown these solutions to be compatible with Welch Allyn endoscopes, providing the manufacturer's directions are adhered to.

Brand Name	Source	Usage
Endozime	The Ruhof Corp.	
Klenzyme	Calgon Vestal Labs	Follow
Enzy-Clean	Burnishine Products	Manufacturer's
Metrizyme	Metrex Research Corp.	Instructions
Enzol	Johnson & Johnson Medical	

NOTE: Other solutions should not be used until a sample has been submitted to Welch Allyn for compatibility testing.

*These solutions must be enzymatic detergents or other cleaning agents specially formulated to clean flexible endoscopes.

WARNING: Prior to disinfection or sterilization, it is imperative that the scope and its components be thoroughly rinsed of any solutions previously used in the cleaning process. The scope and its components should be thoroughly dried. Failure to do so could result in ineffective or incomplete disinfection and sterilization.

CLEANING OF ACCESSORIES

1. Accessories need to be cleaned immediately after each use, since dried blood, mucous or other debris may cause damage to the instrument and interfere with the ability of the user to reprocess the device.
2. Place the accessories in a basin of warm water and a mild enzymatic detergent. Allow these to soak for the time period recommended by manufacturer.
3. Clean by gently wiping with a soft gauze.
4. Rinse all residual detergent from the accessory by immersing it under clean water.

NOTE: All detergent must be removed from all the accessories. Any detergent that remains after the water evaporates can interfere in the subsequent sterilization process.

CAUTION: DO NOT use ultrasonic cleaning methods on the fiberscope itself.

5. Ultrasonic cleaning of accessories is recommended, provided the manufacturer's instructions and the parameters below are followed:

Frequency Range	31-45 kHz
Optimum Frequency	10 kHz
Time	5-10 minutes

NOTE: DO NOT use caustic or abrasive solutions in the ultrasonic cleaner.

6. After cleaning and thoroughly rinsing, the accessories should be gently dried using a soft gauze.

NOTE: Other reusable accessories (channel cleaning adaptors, cleaning brushes, bite block, etc.) and scope components (rubber inlet seals and rubber suction control valves, etc.) may be cleaned in a similar manner as above. Ultrasonic cleaning methods are recommended for accessories and scope components whose entire surfaces are not easily accessible by manual cleaning.

SCHEMATICS

INTERNAL SCHEMATICS OF A WELCH ALLYN ENDOSCOPE

The following internal schematics have been provided to assist users in better understanding the intricate construction of Welch Allyn endoscopes. Knowledge of the various internal channels and tubes within an instrument and their relationship to each other helps facilitate the reprocessing of the endoscope.

The FL-100 intubating fiberscope and its components have been specifically designed for efficient and effective reprocessing before each use by either a manual or automated method.

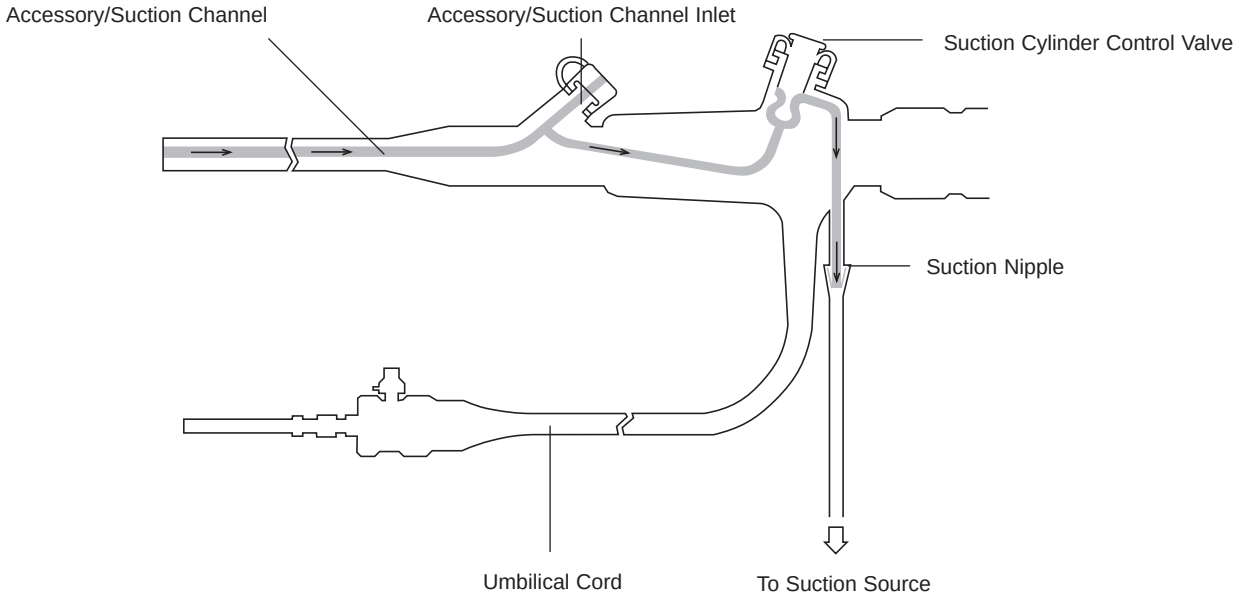
Connectors on all Welch Allyn cleaning/disinfecting adaptors and scope inlet ports incorporate standard size luer-lock and/or luer-slip fittings to easily accommodate reprocessing devices or systems available from other manufacturers.

The internal schematics show that the Welch Allyn cleaning system promotes efficient unidirectional flow of solutions. Starting from the suction nipple at the control body, solutions travel up to the valve cylinder, pass through the channel in the insertion tube and finally exit the channel opening at the distal tip of the scope. The elimination of multiple branching channels, combined with a direct pathway for solutions to travel, maximizes flow efficiency and ensures contact of disinfectant/sterilant with all internally exposed channel surfaces.

WARNING (USA): It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high-level disinfection with an EPA registered sterilant/disinfectant. It should be noted that any endoscope automated reprocessing device or system* must be cleared for marketing by the FDA via the 510 (k) premarket notification or PMA approval process. Only reprocessing solutions/systems satisfying the above conditions and tested and found to be compatible by Welch Allyn should be used with Welch Allyn products.

*Liquid chemical germicides (disinfectants/sterilants) to reprocess medical devices come under FDA regulation and new products must, therefore, undergo a 510 (k) premarket notification submission prior to introduction into interstate commerce.

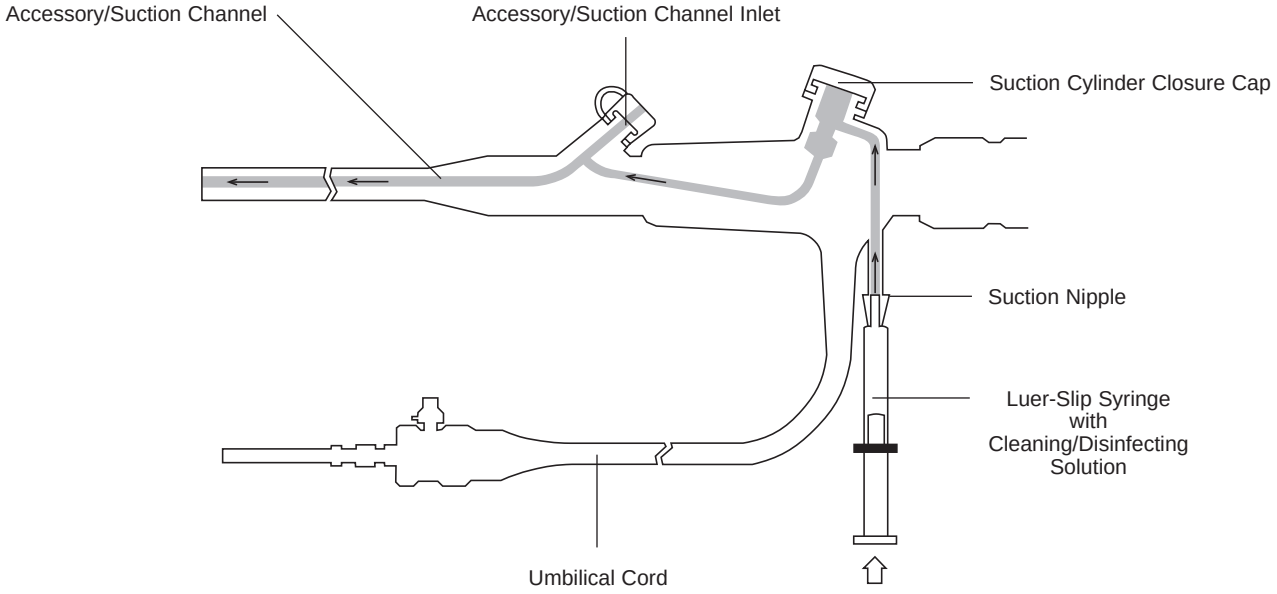
INTERNAL SCHEMATIC OF THE WELCH ALLYN FL-100 INTUBATING FIBERSCOPE



The illustration above shows the entire accessory/suction channel system in the Welch Allyn FL-100 Intubating Fiberscope.

NOTE: All surface areas of the suction system must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

INTERNAL SCHEMATIC SHOWING COMPLETE CLEANING/DISINFECTING SYSTEM



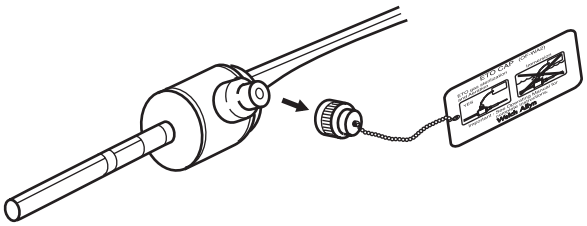
To reprocess the Welch Allyn FL-100 Intubating Fiberscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be used. All internal lumens and all external instrument surfaces and scope components (inlet seal, suction control valve, etc.) need to be exposed to detergent and disinfectant/sterilant. Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

NOTE: All solution entrance ports and flow pathways are illustrated above.

DISINFECTION AND STERILIZATION

HIGH-LEVEL DISINFECTION

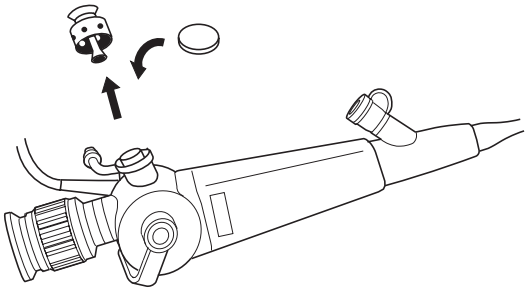
Before disinfecting the endoscope, it must be completely cleaned and dried (see “Care after Each Procedure” on page 12). The user is responsible for determining if the disinfecting techniques described here accomplish the desired clinical effect. Before complete immersion in any disinfecting solution, the endoscope needs to be “Leak Tested” (see page 27).

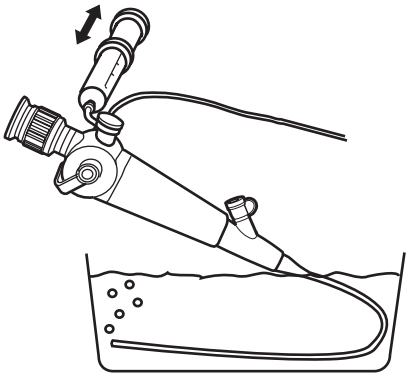


CAUTION: BEFORE IMMERSING:

The “Red” ETO gas sterilization venting cap must be taken OFF.

1. Remove the rubber suction control valve.
2. Install the suction cylinder closure cap as illustrated.
3. a) The suction nipple, located on the control body, is designed with a standard luer slip fitting to accommodate a syringe or other standard device. Fresh disinfecting solution should be drawn into (or flushed through) the entire accessory/suction channel system. The rubber inlet seal should be in place during the flushing process.





WARNING: Avoid introduction of air during this process and confirm that no air bubbles exit the scope tip during flushing (or exit the suction nipple, if aspiration is used). The presence of air bubbles could prevent contact of the disinfectant with channel surfaces.

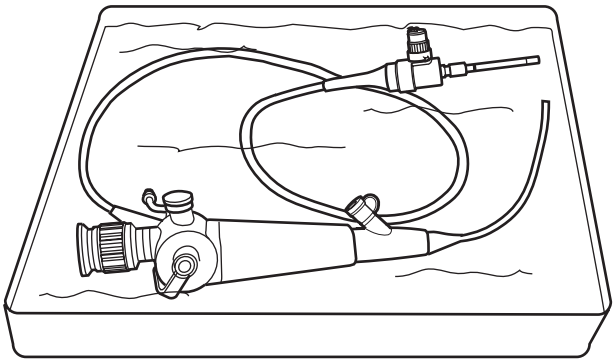
b) While the entire scope is immersed and the suction system is filled with disinfectant, the suction cylinder closure cap and the rubber inlet seal may be removed.

WARNING: It is imperative that ALL internal surfaces of the channels are in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.

NOTE: Please refer to the internal schematics on page 18.

4. While the entire instrument is immersed in disinfecting solution, the syringe used in previous steps can be removed. The entire instrument, however, should remain fully immersed in the disinfecting solution.

5. The endoscope's component parts should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution. Make sure it is left in long enough to accomplish the desired clinical effect.



6. After the endoscope and its component parts have been in contact with the disinfecting solution for the appropriate time, flush the suction system with air to purge remaining disinfectant. Remove the scope and its components from the solution. All residual disinfecting solution must be thoroughly rinsed from the scope and its components with clean water.

7. Remove the suction cylinder closure cap, reinstall the rubber suction control valve and the rubber inlet seal. Thoroughly rinse all outer surfaces of the scope that contacted the disinfecting solution.

8. Attach the scope to an external suction source and aspirate clean water through the channel of the scope. Then, aspirate air through the channel to remove the residual water.

NOTE: 70% alcohol should be flushed through all channels, followed by compressed air, not greater than 24 PSI, to facilitate drying.

NOTE: All final rinses should be made with sterile water.

9. Gently dry all external surfaces of the fiberscope with a soft gauze. Do not put tension on the insertion tube while drying, since the outer cover of the bending section may be excessively stretched. Dry the ocular lens of the eyepiece and the objective lens with a cotton-tip applicator.

COMPATIBLE DISINFECTING SOLUTIONS

Specific reference to brand names is not an endorsement of their efficacy as a disinfecting solution. Tests have shown these solutions to be compatible with Welch Allyn endoscopes, providing the manufacturer's directions are adhered to.

Solution	Brand Name	Source	Usage
Glutaraldehyde	Cidex (14 day)	Johnson & Johnson Medical Inc.	Follow Manufacturer's Instructions
	Wavicide-01	Wave Energy System Inc.	
	Metricide (14 day)	Metrex Research Corp.	
	Omnicide NS	Omnitec Medical Corp.	
	Calgo-Cide 14	Calgon Vestal Labs	
	Sekusept Forte	Henkel	
Aldehyde	Sporcid 10%	Fresenius	
	Tegoment 2%	TH. Goldschmidt	

NOTE: Other solutions should not be used until a sample has been submitted to Welch Allyn for compatibility testing.

NOTE: Please refer to the "General Precautions" on page 2 regarding infection control.

DISINFECTION OF ACCESSORIES

WARNING: Current infection control guidelines require accessories that break the mucosal barrier to be sterilized.

Before disinfecting the accessories, such as bite block, suction control valve, brushes, etc., they must be completely cleaned and dried (see "Care after Each Procedure", page 12). The user is responsible for determining if the disinfecting techniques described here accomplish the desired clinical effect.

1. The accessory should be entirely immersed in disinfecting solution.
2. All accessory surfaces should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and acceptable by the user as appropriate.
3. After it has been immersed in the disinfecting solution for the appropriate amount of time, remove it from the solution.
4. Rinse all residual disinfecting solution from the accessory by totally immersing it in water.
5. After thoroughly rinsing, the accessories should be gently dried using a soft gauze. Compressed air may also be used to facilitate drying.

NOTE: All final rinses should be made with sterile water.

STERILIZATION AND AERATION

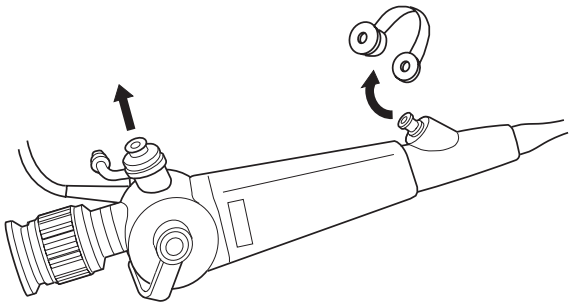
Before sterilizing the fiberscope, it must be completely cleaned and dried (see “Care after Each Procedure”, page 12). The user is responsible for determining if the sterilizing techniques described here accomplish the desired clinical effect.

CAUTION: NEVER place the fiberscope in a steam autoclave!!

NEVER subject the fiberscope to ultrasonic cleaning methods!!

A) ETHYLENE OXIDE GAS STERILIZATION

Ethylene Oxide (ETO) Gas Sterilization can be performed on these endoscopes. The following special instructions, which differ from other endoscopes, must be followed to ensure the proper performance of the instrument.



1. The endoscope must first have been properly cleaned and thoroughly dried (see “Care after Each Procedure”, page 12). Each of the component parts should be removed (suction control valve, rubber inlet seals, etc.).

WARNING: Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.

2. IMPORTANT: Prior to placing the FL-100 Intubating Fiberscope in a gas sterilizer or aeration chamber:

   a) The “Red” ETO Gas Sterilization Venting Cap MUST be “ON” securely.

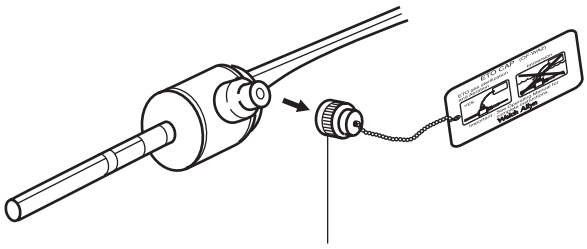
NOTE: This is opposite of the immersion instructions.

   b) Temperature must not exceed 55°C (131°F).

   c) Pressure must not exceed 24 PSI.

   d) Humidity must not exceed 50%.

   e) Sterilization procedure must not exceed 4 hours.



ETO Gas Sterilization Cap

3. Following ETO Gas Sterilization, aeration time of 72 hours at room temperature is required.

4. Aeration Chamber: To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

CAUTION: Prior to placing these endoscopes in an aeration chamber, the “RED” ETO Gas Sterilization Venting Cap MUST be “ON” securely.

B) COLD STERILIZATION

For those situations where Ethylene Oxide (ETO) Gas Sterilization capability is not available, Welch Allyn endoscopes have been designed to withstand immersion in Glutaraldehyde solution for a maximum of 10 hours to achieve “Cold Sterilization”. Never fully immerse a Welch Allyn endoscope without first conducting “Leakage Testing” (see page 27).

CAUTION: NEVER EXCEED 10 HOUR MAXIMUM IMMERSION.

After immersion, the instrument must be thoroughly rinsed to remove all residual Glutaraldehyde solution. After being thoroughly rinsed, Welch Allyn endoscopes must be allowed to “breathe”, balancing internal and external humidity, by attaching the “RED” ETO Venting Cap.

C) OTHER METHODS OF STERILIZATION

In addition to ETO and “Cold Sterilization” techniques, Welch Allyn endoscopes have been found to be compatible** with the Steris Sterilization® System/Process.

**Based upon current data, repeated use of the Steris System could cause fading of the black anodized metallic components of Welch Allyn endoscopes. This discoloration is cosmetic in nature only and continued use should not affect the functionality or watertight integrity of the endoscope.

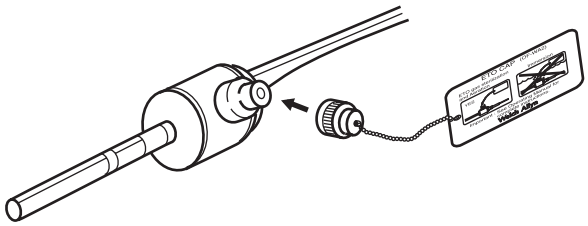
CAUTION: Other types of cleaning and/or sterilization systems/processes are available for the reprocessing of medical devices. However, due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some of these marketed systems/processes/solutions could have detrimental effects on flexible endoscopes.

To avoid the potential for instrument damage, confirm the compatibility of such reprocessing systems/solutions with Welch Allyn prior to use with any Welch Allyn products.

CARE DURING STORAGE

Thoroughly remove all water from the scope and accessories. Be sure both are clean and dry.

1. Prior to storage, remove all valves, inlet seals, etc. to allow thorough drying of internal areas.
2. During storage, the insertion tube of the scope, the umbilical cable and the accessories should be kept as straight as possible.
3. The storage area should be dry and airy. Avoid high humidity, high temperature and areas exposed to the direct rays of the sun.
4. The “RED” ETO Venting Cap should be placed on the scope to allow the scope to “breathe”, balancing internal and external humidity while it is storaged.



WARNING: Prior to storage, it is important that no residual water be left within any internal channels/lumens of the endoscope or accessories. Thoroughly dry all instrument surfaces to reduce the potential for bacteria colonization during storage.

NOTE: 70% Alcohol followed by compressed air, NOT greater than 24 PSI, should be used to facilitate drying of the internal channels.

SERVICING

Before returning any instrument for repair to Welch Allyn, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control.

1. All instruments requiring repair should be shipped in the original carrying case with appropriate packing, along with comments describing the instrument damage and complaint.
2. A repair purchase order number, contact name and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.
3. The “Red” ETO Gas Sterilization Venting Cap needs to be attached to the instrument, when shipped by air freight.
4. Any accessories potentially related to the scope damage or complaint should also be returned with the endoscope.
5. Soaking caps (if applicable) should also be returned with the scope to check/confirm the integrity of their watertight seal.

NOTE: Instrument repairs should only be performed by an authorized Welch Allyn service facility. Welch Allyn assumes no liability for any patient/user injury, instrument damage or malfunction, or reprocessing failure due to repairs made by unauthorized personnel.

CARE AND MAINTENANCE TIPS

Flexible endoscopes have been used to successfully diagnose and treat a wide variety of illnesses for several decades. Progressive design improvements have made current generation flexible endoscopes, such as the Welch Allyn FL-100 Intubating Fiberscope, easier to use, although they are more technologically sophisticated than ever.

To ensure that the instruments are patient-ready and patient-safe, special reprocessing instructions must be followed. To prolong the reliability of the endoscope and prevent instrument malfunction, special care and handling must be exercised. The health-care professionals who actually care for and reprocess flexible endoscopes are ultimately responsible for ensuring safe and reliably functioning instruments.

Tremendous efforts have been made in designing instruments that can be reprocessed and maintained as easily as possible. However, due to the nature of their use and application, flexible endoscopes must be subjected to special cleaning procedures, followed by a disinfection or sterilization process after every patient use.

Welch Allyn strongly recommends that users review the following suggestions and advice on the care and maintenance of your Welch Allyn endoscopes. However, these tips, particularly those involving scope reprocessing, should not be interpreted as “shortcuts” and are not intended to substitute directions for the complete instructions found elsewhere in the owner’s manual.

- Avoid soaking the endoscope with accessories (forceps, injection or aspiration needles, etc.) or any sharp-edged object which could inadvertently scratch or cut the distal bending section sheath. (Subsequent flexing back and forth of the rubber sheath could eventually stretch the scratched rubber until a pinhole and leak develops.)
- Exposure to a compatible enzymatic detergent is essential for thorough cleaning of all surfaces of the endoscope. Rinsing and drying after cleaning is imperative to prevent dilution of the disinfectant/sterilant.

- Do NOT reuse disposable accessories intended for single patient or one-time use.
- Do NOT expose the endoscope or accessories to harsh chemical solutions. Strictly adhere to exposure times recommended by the manufacturers of compatible solutions.
- Avoid contact of any flexible portion of the endoscope with any sharp-edged objects (bed frames, table top corners, sink drains, accessories hanging in storage cabinets, etc.) at any time during the handling, reprocessing or storage of the endoscope.
- Avoid stretching of the bending section rubber sheath at the distal portion of the scope. During mechanical cleaning of the scope with a dampened gauze, do not use excessive force. A gentle back and forth wiping motion should be sufficient to remove gross debris. Subsequent soaking in an enzymatic detergent will clean the remainder of debris.
- Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.
- Avoid attempting to remove or unscrew scope components which should not be removed. Parts such as the distal portion of the light guide plug and any rubber strain reliefs on either the insertion tube or umbilical cable are essential to the watertight integrity of the instrument. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the endoscope.
- Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with an endoscope. Some units may have sharp-edged wire mesh filters and baskets or inlet/outlet ports which could damage your scope.
- Do NOT introduce air bubbles into the scope's internal channels during flushing of cleaning and/or disinfecting/sterilizing solutions as these bubbles could interfere in the effectiveness of the disinfection/sterilization process.
- Do NOT store the endoscope and accessories in the carrying case. This type of dark, humid and unventilated environment is conducive to bacteria colonization, which increases the risk of cross-contamination.
- Prior to each use, check the condition of all accessories.

Do NOT use any accessories with kinked or bent flexible shafts.

Do NOT use forceps with misaligned cups and/or bent needles/spikes.

Do NOT use aspiration or injection needles which are not retractable or whose sharp tips cannot be protected.

Do NOT use cleaning brushes without smooth or rounded distal tips.

Use of any of the above accessories could result in channel damage and costly repairs.

- Verification of the efficacy level of glutaraldehyde (via test strips or similar methods) is recommended to ensure potency of glutaraldehyde to achieve high-level disinfection.
- Instrument repairs should only be performed by an authorized Welch Allyn service facility. Welch Allyn assumes no liability for any patient/user injury, instrument damage or malfunctions, or reprocessing failure due to repairs made by unauthorized personnel.

LEAKAGE TESTER INSTRUCTIONS

The leakage test is a simple two (2) stage test of the watertight integrity of the instrument. Air pressure is introduced into the interior of the instrument via a hand pump. The FL-100 scope is then checked for pressure decay by using a pressure gauge. A secondary visual check is also performed.

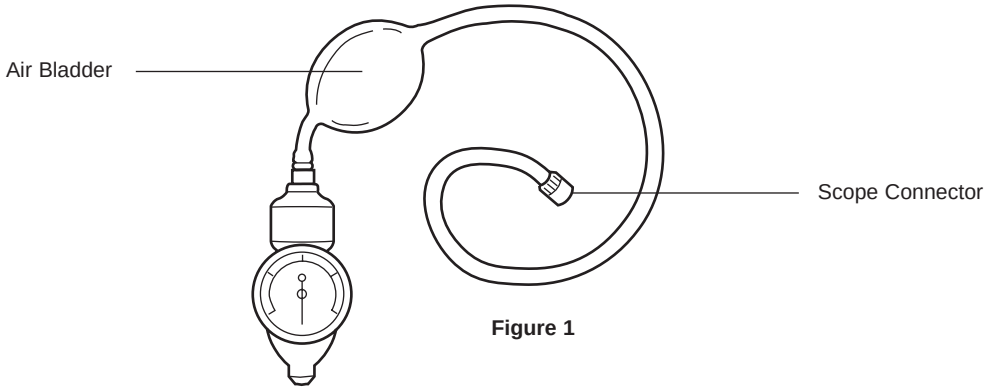


Figure 1

DRY TEST, STAGE I

BEFORE IMMERSION, Welch Allyn endoscopes should be tested for any loss of integrity in their watertight construction (example: major tear in accessory/suction channel).

1. Remove the Red ETO Vent Cap from the light guide. The leakage tester connector and the air vent on the light guide MUST be completely dry before connecting the Leakage Tester.
2. Secure the Leakage Tester connector to the air vent on the scope's light guide (where the Red ETO Vent Cap was removed).
3. Confirm that the pressure indicator is at "0".

NOTE: Make sure the pressure release valve on the back of the gauge is closed before squeezing the gauge bulb.

4. Pressurize the scope by pumping the hand bulb until the indicator on the gauge is in the GREEN zone (0.16-0.20 kg/cm^2).

NOTE: During the leak test procedure, the insertion tube of the scope should be flexed in various positions and the distal bending section should be fully angulated in all directions to confirm the absence of a leak.

DO NOT pressurize into the RED Danger zone. Doing so may cause serious damage to the scope (Figure #3).

5. Observe the gauge pressure to determine if the indicator remains in the GREEN zone. If the indicator drops from the GREEN zone rapidly, a major leak is indicated.

NOTE: NEVER IMMERSE the entire instrument if the gauge indicator does not remain in the GREEN zone. Instead, contact your Welch Allyn Service Center.

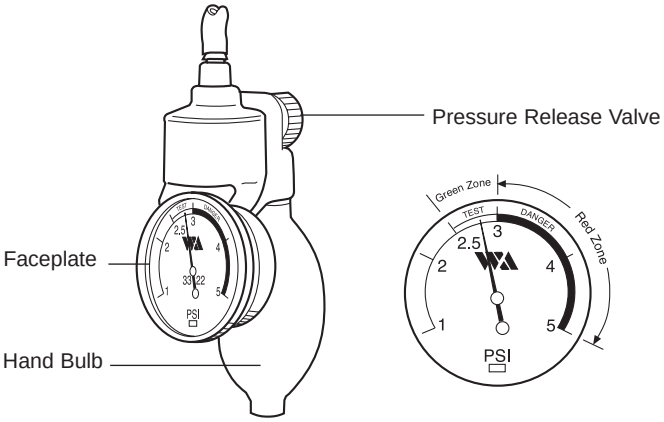


Figure 2

Figure 3

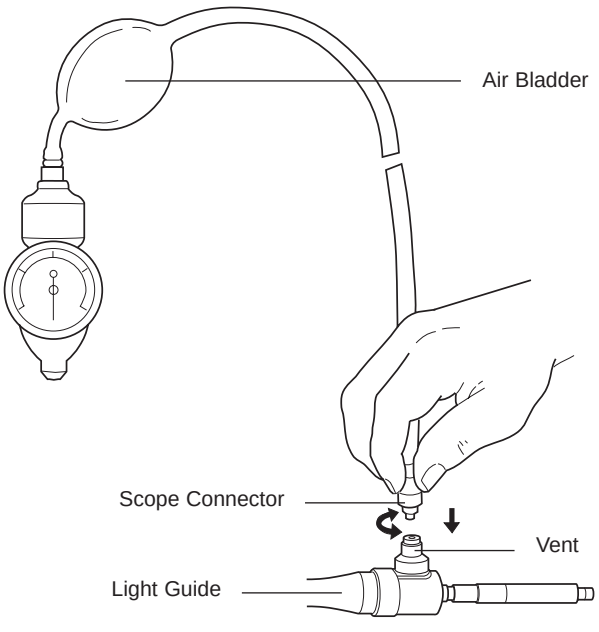


Figure 4

WET TEST, STAGE II

After determining that there are no major leaks in Stage I testing, Welch Allyn endoscopes may be immersed in clean water to test for loss of integrity in the watertight construction.

1. With the Leakage Tester securely attached to the scope and the scope pressurized with the gauge indicator in the GREEN zone, the entire scope may be immersed in clean water (Figure #5).

NOTE: Only the Leakage Tester connector and a small portion of its tubing should be immersed. NEVER immerse the entire Leakage Tester.

2. Observe the instrument carefully while deflecting the distal tip of the scope in all directions. A few bubbles may initially occur from recessed areas of the scope. This is normal. If a continuous stream of bubbles is observed from the same location, a leak is indicated. **DO NOT use the scope!** Immediately remove it from the water (Figure #6).

3. After removing the scope from water, release the air pressure within the scope by opening the pressure release valve on the handle of the Leakage Tester. After the gauge indicates “zero”, disconnect the Leakage Tester from the scope.

NOTE: NEVER connect or disconnect the Leakage Tester under water. This will cause leakage of water into the scope and Leakage Tester. This can cause damage to both instruments.

4. If leakage was discovered, thoroughly dry the instrument and contact your Welch Allyn Service Center.

5. If no leakage was discovered, you may proceed with cleaning and disinfection of the scope as described in the Owner’s Manual.

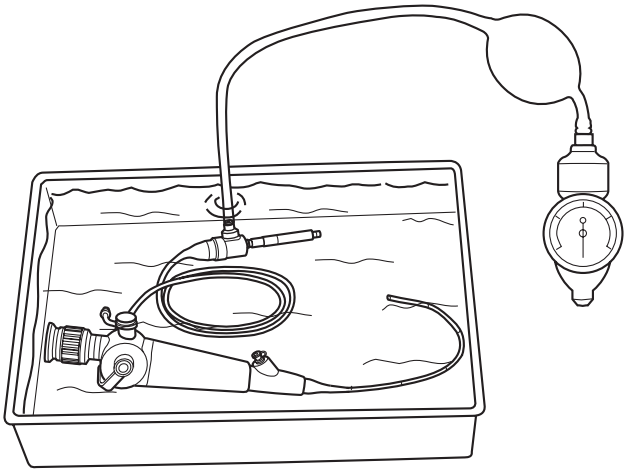


Figure 5

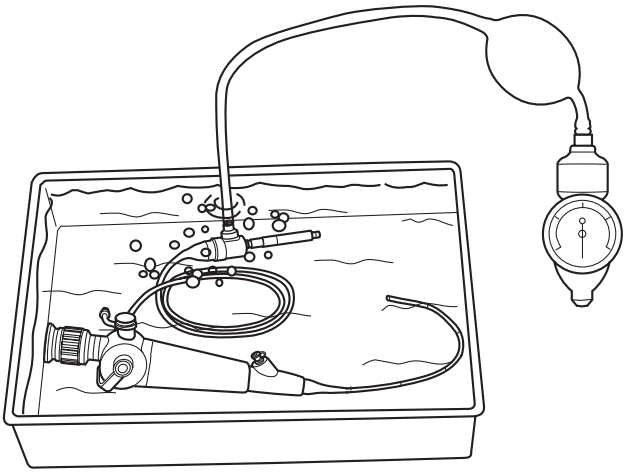


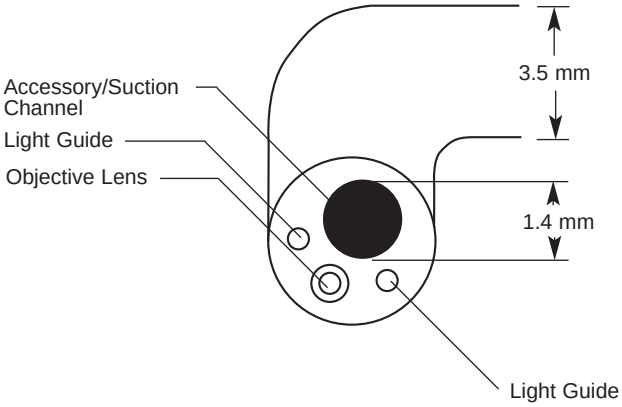
Figure 6

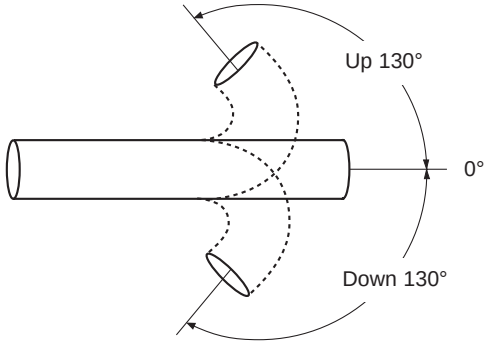
SPECIFICATIONS

Angle of View	90°
Depth of Field	3-50 mm
Diopter	+2 to -8 dptr.
Tip Deflection	Up 130°, down 130°
Rigid Distal Diameter	3.4 mm
Insertion Tube Diameter	3.5 mm
Diameter of Accessory/Suction Channel	1.4 mm
Insertion Tube Working Length	600 mm
Total Length	800 mm

NOTE: Specifications are subject to change without notice.

DISTAL END





DISTAL TIP **BENDING SECTION**

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